**UNITED STATES ENVIRONMENTAL PROTECTION AGENCY**
**WASHINGTON, D.C. 20460**

EPA United States Environmental Protection Agency **Office of Pesticide Programs**

**Antimicrobials Division (AD)**

March 12, 2015

| | |
|---|---|
| DP BARCODE: | 422253 |
| MRID: | 49433200, 49433201 and 49433202, 49543200, and 49543204 |
| SUBJECT: | surpHace pHresh CONCENTRATE |
| REG. NO.: | 90863-R |
| DOCUMENT TYPE: | Product Chemistry Review |
| Manufacturing-use [ ] | OR End-use Product [X] |

INGREDIENTS:

| PC Code(s) | CAS Number | Active Ingredient: |
|---|---|---|
| 078001 | 7664-93-9 | Sulfuric Acid |

| | |
|---|---|
| TEST LAB: | Product Safety Labs |
| SUBMITTER: | Phresh Technologies LLC |
| GUIDELINE: | OPPTS 830 Guidelines<br>Product Chemistry Group A and B |
| ORGANIZATION: | AD\PSB\CTT |
| REVIEWER: | Lynette T. Umez-Eronini |
| APPROVED BY: | Karen P. Hicks |
| APPROVED DATE: | March 12, 2015 |
| COMMENT: | Inerts are approved for food use in antimicrobial formulations. |

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MEMORANDUM

SUBJECT: Product Chemistry Review for EPA Reg. 90863-R
Product Name: surpHace pHresh CONCENTRATE
DP Barcode: 422253

FROM: Lynette T. Umez-Eronini, Chemist
Chemistry and Toxicology Team
Product Science Branch
Antimicrobials Division (7510P)

THRU: Karen Hicks, Team Leader
Chemistry and Toxicology Team
Product Science Branch
Antimicrobials Division (7510P)

TO: Jacqueline Hardy PM#34/Thomas Luminello
Regulatory Management Branch II
Antimicrobials Division (7510P)

Applicant: Phresh Technologies LLC

CODE: (A540) New Product; Non-Fast Track;

DATE DUE: April 13, 2015

PRODUCT FORMULATION FROM LABEL:

| Active Ingredient(s): | % by wt. |
|---|---|
| Sulfuric Acid | 19.67 |
| Inert Ingredients: | 80.33 |
| Total: | 100.00 |

BACKGROUND:

The consultant, Brennis Consulting Services LLC, on behalf of the registrant, Phresh Technologies LLC has submitted an application for registration of an integrated end-use product, called surpHace pHresh CONCENTRATE. The product is a sanitizer for equipment, pipelines, tanks, and food processing plants. "surpHace pHresh CONCENTRATE" is for food use.

The product chemist reviewed the following data package:

1. Cover letter, July 21, 2014
2. Application for Pesticide Registration (EPA Form 8570-1), July 21, 2014.
3. Two Basic Confidential Statements of Formula (CSF) (EPA Form 8570-4), July 16, 2014.
4. Certification with Respect to Citation of Data (EPA Form 8570-34), July 24, 2014.
5. Data Matrix, July 21, 2012, 3 pages.
6. Product Label, June 24, 2014.
7.

| | |
|---|---|
| 49433200 | Phresh Technologies, LLC (2014) Submission of Product Chemistry, Toxicity and Efficacy Data in Support of the Application for Registration of surpHace pHresh Concentrate. Transmittal of 10 Studies. |
| 49433201 | Brennis, R. (2014) surpHace pHresh Concentrate: Product Identity and Composition, Beginning Materials, Production Process, Formation of Impurities, Certified Limits, and Analytical Method. Unpublished study prepared by Brennis Consulting Services. 20p. |
| 49433202 | Zehr, P. (2014) surpHace pHresh Concentrate: Physical and Chemical Characteristics: Color, Physical State, Odor, pH, Viscosity, and Density/Relative Density. Project Number: 38129, P801, 140128/6H. Unpublished study prepared by Product Safety Laboratories. 15p |
| 49543200 | Cover letter from Registrant to EPA, January 2, 2015, same as Transmittal Letter: Phresh Technologies, LLC (2015) Submission of Data in Support of the Application for Registration of surpHace pHresh Concentrate. Transmittal of 4 Studies. |
| 49543204 | Wo, C. (2015) surpHace pHresh CONCENTRATE: Preliminary Analysis, Active Ingredient Only. Project Number: 38128, P809/AI, 140128/6H. Unpublished study prepared by Product Safety Laboratories. 14p |

8. Basic CSF, January 14, 2015.

9. Certificates of analysis for each of the two active ingredients (sent via e-mail 1/30/2015).

FINDINGS:

1. Basic CSF, July 16, 2014 is obsolete and is superseded by Basic CSF, January 14, 2015.
2. The nominal concentration of the active ingredient on the CSF is consistent with the product label.
3. All ingredients in this formulation are approved for food-use in pesticide formulations.
4. Note: In MRID 49433201, page 5 of 13, the name of the active ingredient inadvertently reads "Sodium Chlorite." It should read **Sulfuric Acid**.
5. Group A product chemistry data requirements applicable to end-use products have been met (see MRID# 49432001 and 49432002, Certificates of Analysis, and Table A below).
6. Group B product chemistry data requirements applicable to end-use products have been met (see EPA Form 8570-36, December 22, 2014 and Table B below), with the exception of OPPTS 830.6317 (Storage Stability) and OPPTS 830.6320 (Corrosion Characteristics) studies. The unmet data requirements would be sent upon completion.

CONCLUSION:

The Basic CSF, January 14, 2015 is acceptable and supersedes previous Basic CSF for the same product. Group A Product Chemistry data requirements have been met. Group B Product Chemistry data requirements have been met, with the exception of the Storage Stability and the Corrosion Characteristics studies. The unmet data requirements are to be submitted to the agency upon completion.

## PRODUCT CHEMISTRY REVIEW

I. CONFIDENTIAL STATEMENT OF FORMULA

a. Type of formulation and source registration:

- Non-integrated formulation system — Yes [ ] No [X]
- Are all TGAIs used registered? — Yes [ ] No [X]
- Integrated formulation system — Yes [X] No [ ]
- If "ME-TOO," specify EPA Reg. No. of existing product:

b. Clearance of inerts for non-food or food use:
The product is cleared for food use under 40 CFR §180.940 and §180.950.

Yes [X] No [ ]

c. Physical state of product: Liquid

d. The chemical IDs and analytical information (including that for the TGAIs), density, pH, and flammability are consistent with that given in 830 Series, Group B.

Yes [X] No [ ]

e. The NCs and CLs are acceptable. Yes [ ] No [X]

| f. Active ingredient | NC(%) | LCL(%) | UCL(%) |
|---|---|---|---|
| Sulfuric Acid | 19.67 | 18.69 | 20.65 |

g. For products produced by an integrated formulation system:

- Do all impurities of toxicological significance have a UCL?
  Yes [ ] No [ ] Not applicable [X]
- Have all impurities of ≥ 0.1% in the product been identified?
  Yes [ ] No [ ] Not applicable [X]

II PRODUCT LABEL

a. The active ingredient statement (chemical IDs and NC) is consistent with the CONFIDENTIAL STATEMENT OF FORMULA. Yes [X] No [ ]

b. The formula contains one of the following:

- 10% or more of a petroleum distillate: Yes [ ] No [X]
- 1.0% or more of methyl alcohol: Yes [ ] No [X]
- sodium nitrite at any level: Yes [ ] No [X]
- a toxic List 1 inert at any level: Yes [ ] No [X]
- arsenic in any form: Yes [ ] No [X]

c. If "yes" to any of the above, does the inert ingredients statement contain a footnote indicating this?

Yes [ ] No [ ] Not applicable [X]

d. Appropriate warning statement(s) regarding flammability or explosive characteristics of the product are listed on the label.

Yes [ ] No [ ] Not applicable [X]

e. The storage and disposal instructions for the pesticide container are in compliance with PR Notice 84-1 for household use products or PR Notice 83-3 for all other uses.

Yes [X] No [ ]

f. The product requires an expiration date at which time the NC falls below the LCL (based on the 1-year storage stability data or other information).

Yes [ ] No [ ]

**Table A:**
**Product Chemistry (Series 830, Group A)**

| Data Requirements | Acceptance of Information | MRID No. |
|---|---|---|
| 830.1550 Product Identity[1] | A | 49433201 |
| 830.1600 Description of Materials | A | 49433201 |
| 830.1620 Production Process[2] | A | 49433201 |
| 830.1650 Formulation Process[3] | A | 49433201 |
| 830.1670 Formation of Impurities[4] | A | 49433201 |
| 830.1700 Preliminary Analysis[5] | A | 49543204 and Certificates of Analysis |
| 830.1750 Certified Limits[6] | A | 49432001 |
| 830.1800 Enforcement Analytical Method[7] | A | 49432002 |
| 830.1900 Submittal of Samples | A | 49543204 |

Explanation: A=acceptable; N=not acceptable (i.e., item was submitted but is not acceptable); NA=technically not applicable (i.e., not required); G=data gap (i.e., item was not submitted but is required); U=requires upgrading (i.e., item is unacceptable but upgradeable); W=waived; E=EPA estimate.

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[1]See Confidential Appendix A for additional information.
[2]For MP/EP products produced by an integrated formulation system.
[3]For products from a TGAI or MP.
[4]May be waived unless actual/possible impurities are of toxicological concern.
[5]Five batch analysis required for products produced by an integrated formulation system.
[6]If different from standard CLs recommended in 40 CFR 158.175, this should be discussed in Confidential Appendix A.
[7]Abbreviate method used as follows: gas chromatography (GC), infrared (IR), ultraviolet absorption (UV), nuclear magnetic resonance (NMR), etc.

**Table B:**
**Physical and Chemical Characteristics (Series 830, Group B)**

| Physical/Chemical Properties* | Acceptance of Data | Value or Qualitative Description | MRID No. |
|---|---|---|---|
| 830.6302 Color | NA | | |
| 830.6303 Physical State | A | Liquid | 49433202 |
| 830.6304 Odor | NA | | |
| 830.6313 Stability to Normal and Elevated Temperatures, Metals, and Metal Ions | NA | | |
| 830.6314 Oxidation/ Reduction; Chemical Incompatibility | A | The product is not an oxidizing or reducing agent. | Data Matrix |
| 830.6315 Flammability/ Flame Extension | A | This product contains no flammable liquids. | Data Matrix |
| 830.6316 Explodability | A | This product is not potentially explosive. | Data Matrix |
| 830.6317 Storage Stability | G | This data is being conducted and will be submitted when complete. | Data Matrix |
| 830.6319 Miscibility[1] | A | This product is not an emulsifiable liquid that is to be diluted with petroleum solvent. | Data Matrix |
| 830.6320 Corrosion Characteristics | G | This data is being conducted and will be submitted when complete. | Data Matrix |
| 830.6321 Dielectric Breakdown Voltage | A | This product is not for use around electrical equipment. | Data Matrix |
| 830.7000 pH[2] | A | 1.68 | 49433202 |
| 830.7050 UV/Visible Absorption | NA | | |
| 830.7100 Viscosity | A | 1.4 Centistokes (20°C)<br>0.9 Centistokes (40 °C) | 49433202 |
| 830.7200 Melting Point/Melting Range | NA | | |
| 830.7220 Boiling Point/Boiling Range | NA | | |
| 830.7300 Density/Relative Density/Bulk Density | A | 1.128 g/mL | 49433202 |
| 830.7370 Dissociation Constants in Water | NA | | |
| 830.7550/830.7560/830. 7570 Partition Coefficient | NA | | |

| Physical/Chemical Properties* | Acceptance of Data | Value or Qualitative Description | MRID No. |
|---|---|---|---|
| 830.7840/830.7860 Water Solubility | NA | | |
| 830.7950 Vapor Pressure | NA | | |

Explanation: A=acceptable; N=not acceptable (i.e., item was submitted but is not acceptable); NA=technically not applicable (i.e., not required); G=data gap (i.e., item was not submitted but is required); U=requires upgrading (i.e., item is unacceptable but upgradeable); W=waived; E=EPA estimate.

* Provide brief description, e.g., color – yellow or property value, e.g., density 1.25 g/cc. unless otherwise indicated, the property should be at 25°C.

[1]If product is an emulsifiable liquid

[2]If product is dispersible with water